

Appendix D

Consumer research methodology and results

Health Claims Communication Study

- Analysis of Findings -

Prepared For:



U.S. Canola Association

A Golden Opportunity for Our Nation's Health

Prepared By:



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Introduction

RESEARCH OBJECTIVES

The objective of this study is to determine if the alternate claims are equal to or better than a claim consistent with the FDA approved claim for olive oil. To be recommended to the FDA for consideration, the alternate claim must be at least as clear at communicating the desired message, while conveying the same level of uncertainty.

METHODOLOGY/DATES/SAMPLE

The study was conducted over the Internet, using the consumer panel from Greenfield Online. The sample of panelists for this study were selected to yield a nationally representative sample of households, stratified by the four major Census regions.

The total sample size for this project was 1012 respondents which was split into five cells. Each respondent evaluated one of the four alternate statements or the one based on the FDA approved claim for olive oil also referred to in this study as the 'FDA Generic statement'. Each respondent then compared the exposed alternate statement to the FDA Generic statement on clarity and believability.

The sample specifications for this project are as follows:

- 50% male / 50% female
- Age 21-64 distributed proportionately according to U.S. Census
- Minimum of 8% Hispanic and 10% African-American
- Interview dates were August 30, 2005 to September 6, 2005

STATISTICAL TESTING

The data in this analysis were tested at the 95% confidence level. Uppercase letters indicate differences at 95%.





Canola Oil Claims

Uncertainty Remains

Canola oil (19 grams - about 1½ tablespoons per day) may reduce the risk of coronary heart disease due to its unsaturated fat content. Canola oil should replace a similar amount of saturated fat in the diet without increasing calories. FDA has determined that although some scientific uncertainty remains, the weight of the evidence supports this conclusion.

Data are Limited

Canola oil (19 grams - about 1½ tablespoons per day) may reduce the risk of coronary heart disease due to its unsaturated fat content. Canola oil should replace a similar amount of saturated fat in the diet without increasing calories. FDA has concluded that while the scientific data are limited, the majority of available evidence supports this statement.

Suggests, But Does Not Prove

Canola oil (19 grams - about 1½ tablespoons per day) may reduce the risk of coronary heart disease due to its unsaturated fat content according to scientific evidence that suggests but does not yet prove this benefit. Canola oil should replace a similar amount of saturated fat in the diet without increasing calories.

Supportive, But Not Conclusive

Canola oil (19 grams - about 1½ tablespoons per day) may reduce the risk of coronary heart disease due to its unsaturated fat content according to supportive but not conclusive research. Canola oil should replace a similar amount of saturated fat in the diet without increasing calories.

FDA Generic

Eating about 1½ tablespoons (19 grams) of canola oil daily may reduce the risk of coronary heart disease due to the unsaturated fat in canola oil. FDA evaluated the data and determined that, although there is research supporting the claim, the evidence is not conclusive. To achieve this possible benefit, canola oil should replace a similar amount of saturated fat and not increase the total number of calories you eat in a day.





Executive Summary

- None of the alternative Canola Oil statements achieves the action standard of being more clear and easy to understand to the consumer than the FDA Generic statement while conveying the same level of uncertainty.
- Suggests, but Does Not Prove, however, is comparable to the FDA Generic claim in terms of clarity, conveyance of uncertainty, and believability which may lend itself best to being the alternative version recommended to the FDA.
- Another alternative statement, Supportive, but Not Conclusive, is also comparable to the FDA Generic claim in terms of clarity and conveyance of uncertainty, but it is actually more believable than the FDA Generic regarding the link to heart disease which may not be viewed favorably by the FDA.



Summary of Statistical Comparisons To FDA Generic Claim At The 95% Confidence Level

	Uncertainty Remains	Data are Limited	Suggests, But Does Not Prove	Supportive, But Not Conclusive
Clarity (<i>Monadic – Top-Two-Box</i>)				
Clarity - Paired Preference (Among Total Sample)				
Believability (<i>Monadic – Top 2 Box</i>)	↑	↑		
Believe Link to Heart Disease (<i>Monadic – Top 2 Box</i>)	↑			↑
Believability - Paired Preference (Among Total Sample)				
Author's Certainty Rating (<i>Comparative Monadic – Top 2 Box</i>)	↑	↑		
Author's Certainty Rating (<i>Monadic – Top-2-Box</i>)	↑	↑	↑	

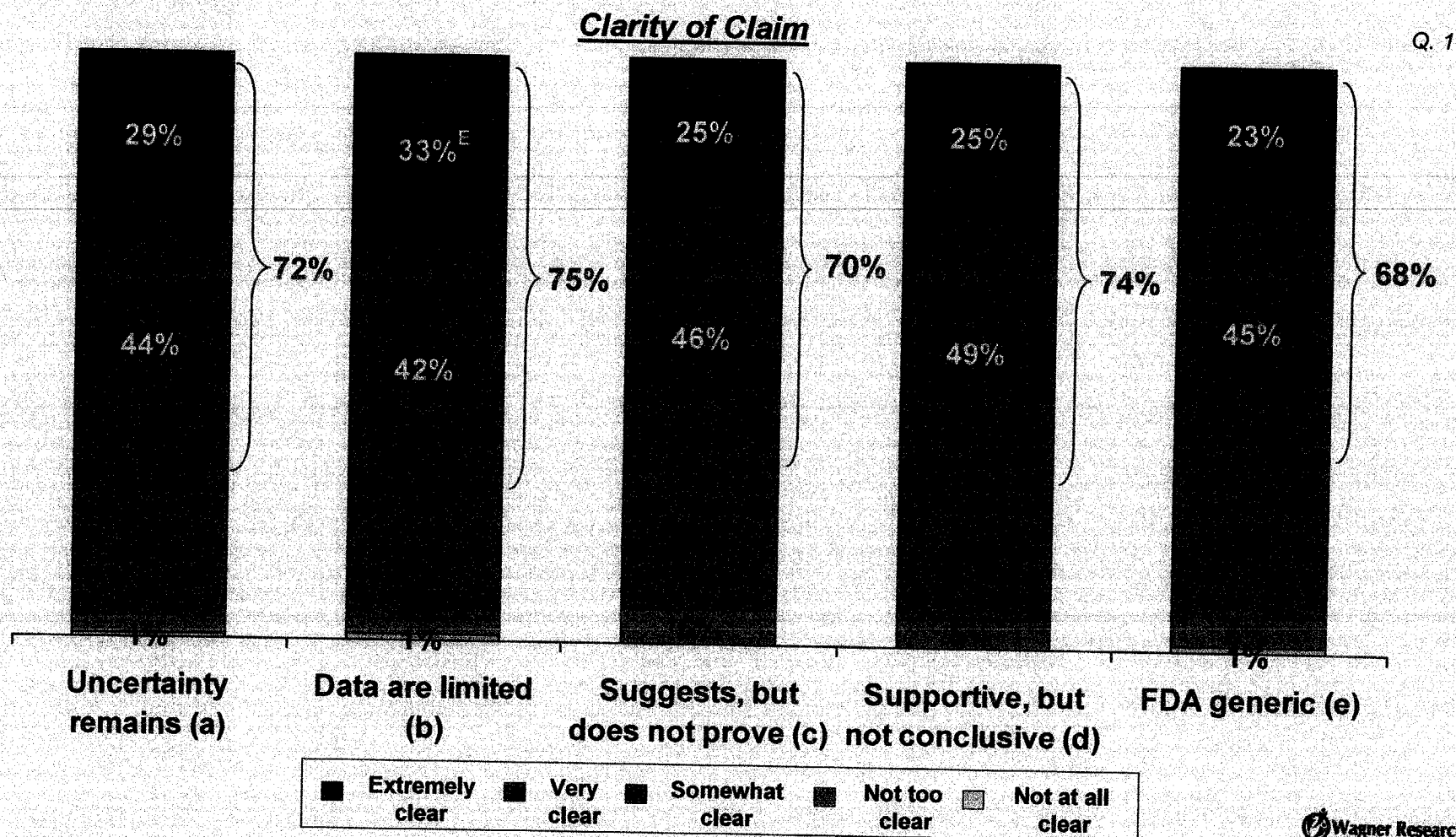
↑ = significantly higher at the 95% confidence level than the FDA Generic claim
 ↓ = significantly lower at the 95% confidence level than the FDA Generic claim

Key Findings



Clarity of Claim – Monadic Scores

- On a monadic basis with no point of comparison, all four alternate statements are viewed as being just as clear and easy to understand as is the FDA Generic statement.



Base: Total Rated Claim (Monadic) – approximately 200 per claim

Uppercase letters indicate a significant difference at the 95% confidence level (a/b/c/d/e)

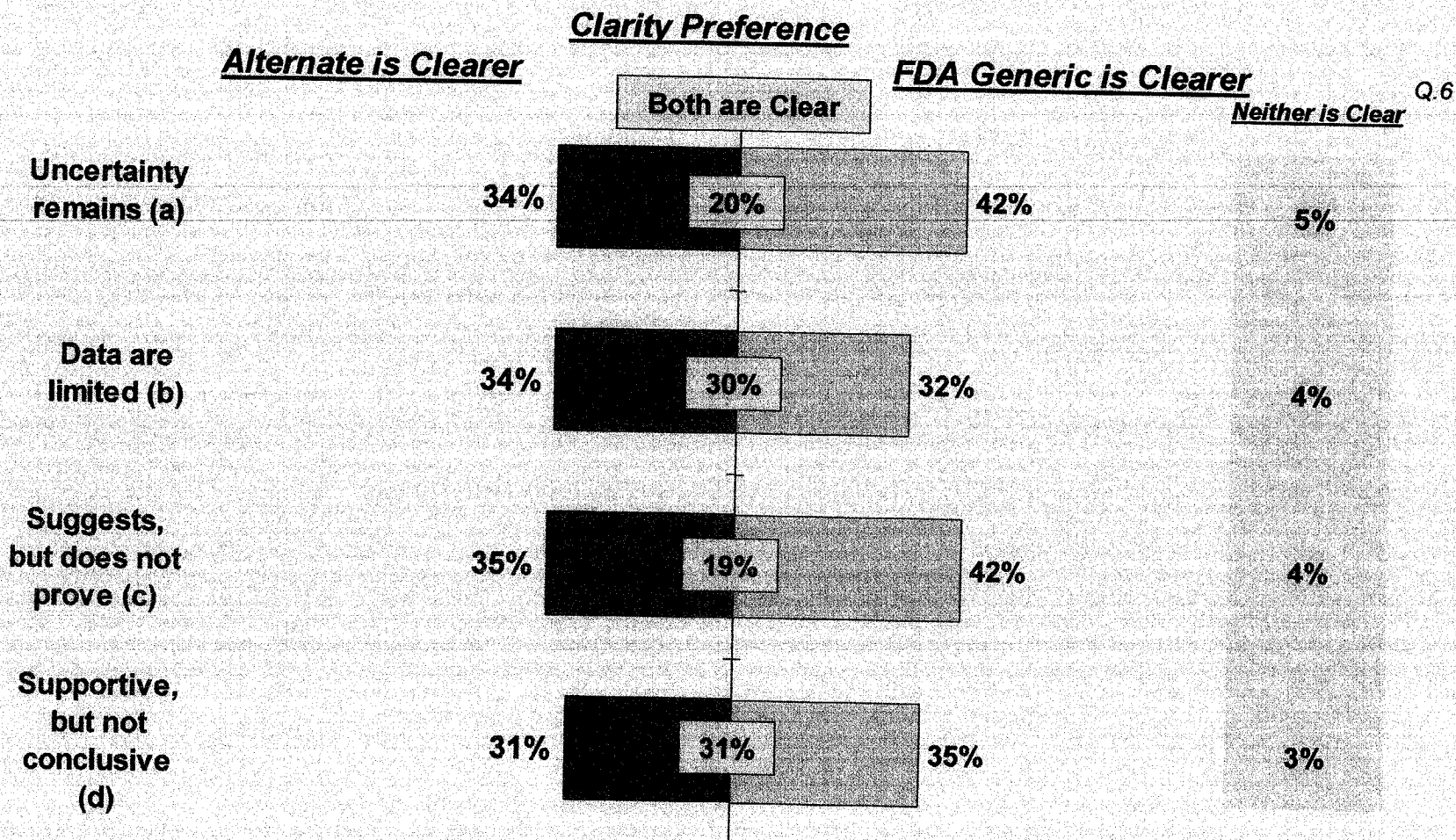


"Health Claims" Study (# 05_080)



Clarity of Claim vs. FDA Generic -- Preference Score

- Each statement was presented side-by-side with the *FDA Generic* for a direct comparison of the clarity of the statement. All four alternate statements are seen as being similar to the *FDA Generic* in terms of clarity.



Base: Saw Pair Preference – data was weighted to reflect an equal proportion for each monadic claim seen first or second.
 *^ - Indicate a significant preference at the 95% confidence level between the FDA approved statement and the alternate claim.
 * - Among Total
 ^ - Among those with a preference

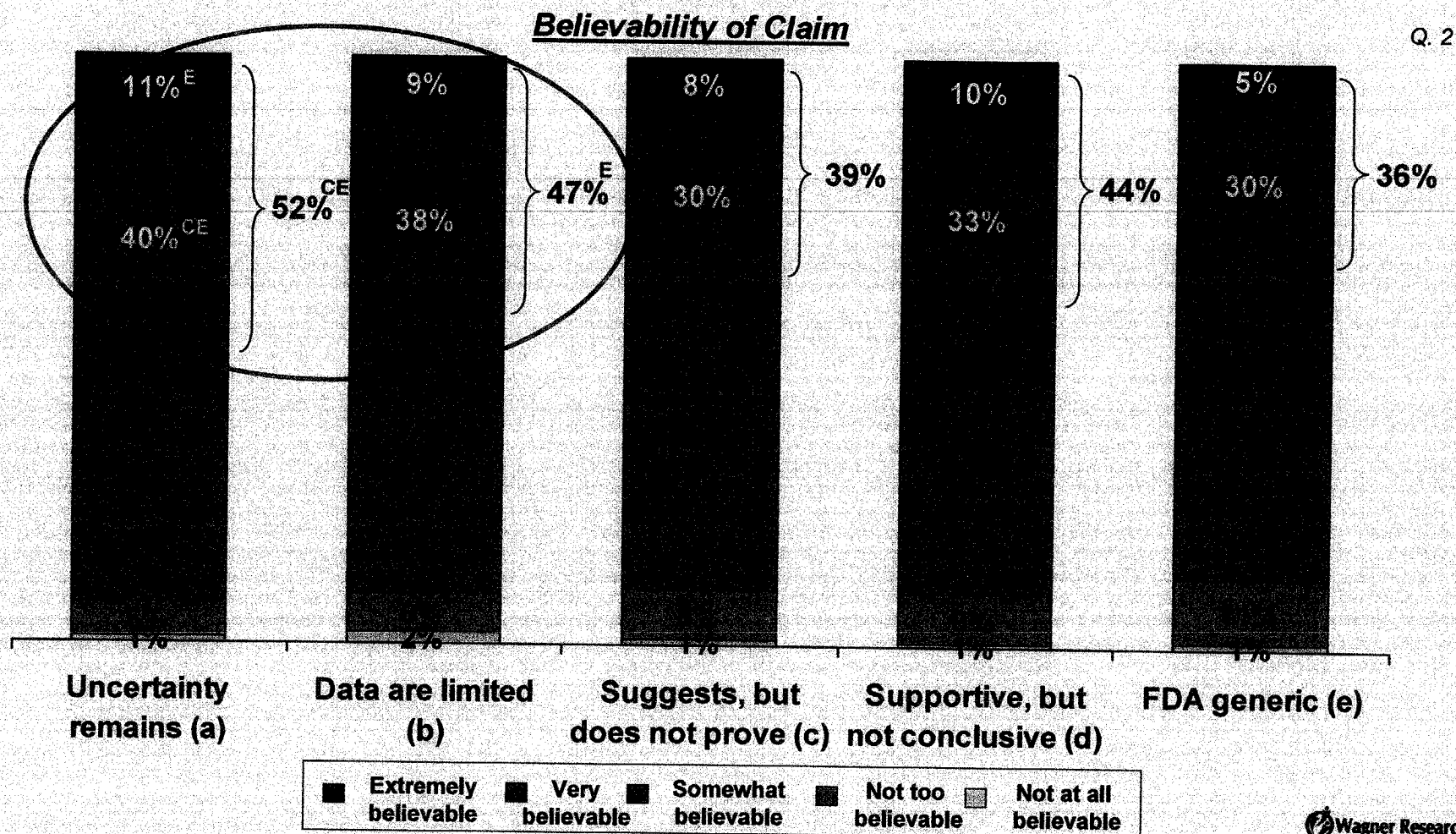


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Believability of Claim – Monadic Scores

- On a monadic basis, with no point of comparison, two of the claims, Suggests but Does Not Prove and Supportive, but Not Conclusive are equally as credible as the FDA Generic while the other two are actually more believable.



Base: Total Rated Claim (Monadic) – approximately 200 per claim

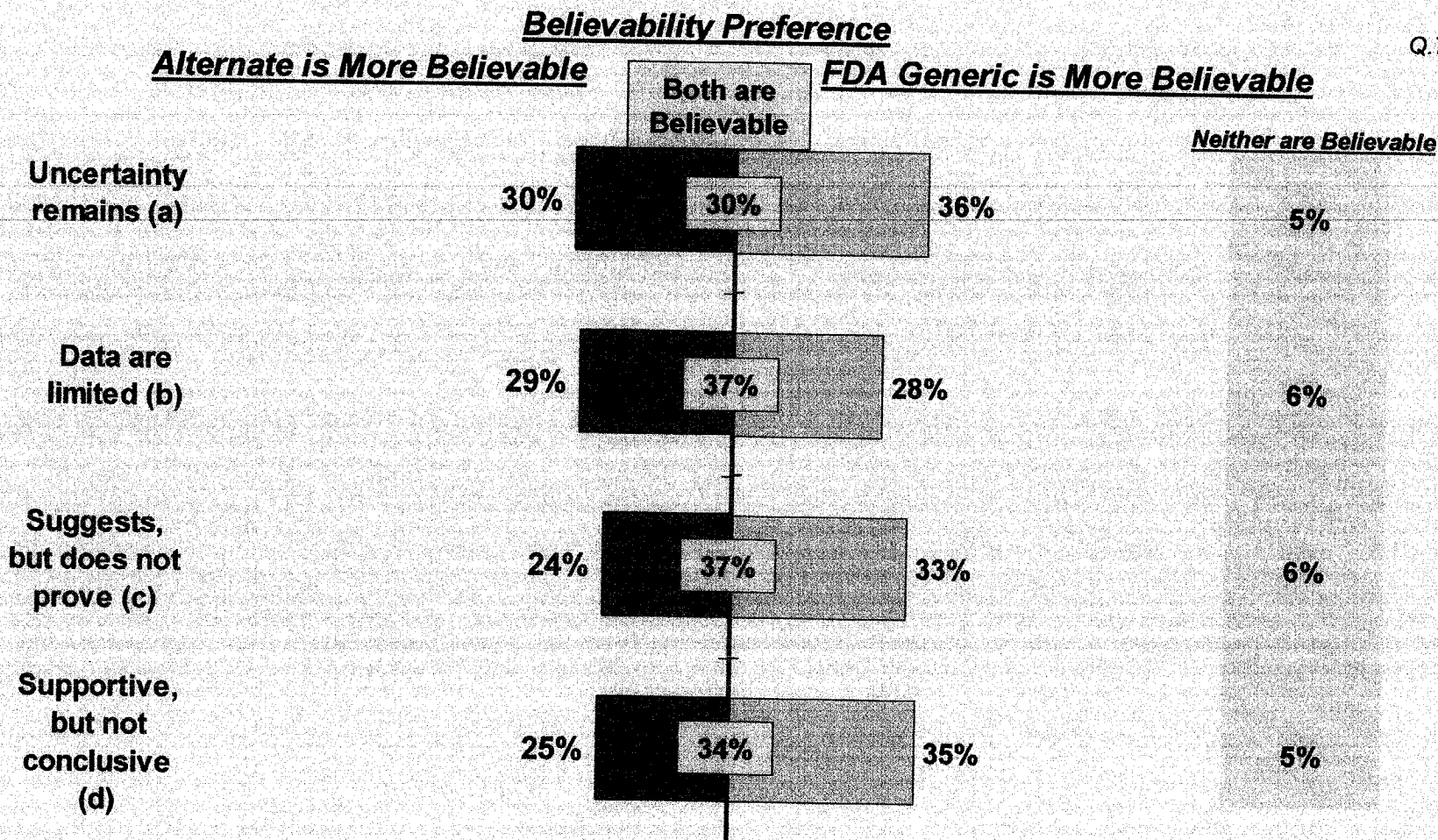
Uppercase letters indicate a significant difference at the 95% confidence level (a/b/c/d/e)





Believability of Claim vs. FDA Generic – Preference Scores

- However, on a head-to-head comparative basis, all four alternate statements are seen as being just as believable as the FDA Generic statement.



Base: Saw Pair Preference – data was weighted to reflect an equal proportion for each monadic claim seen first or second.

*^ - Indicate a significant preference at the 95% confidence level between the FDA approved statement and the alternate claim.

* - Among Total

^ - Among those with a preference

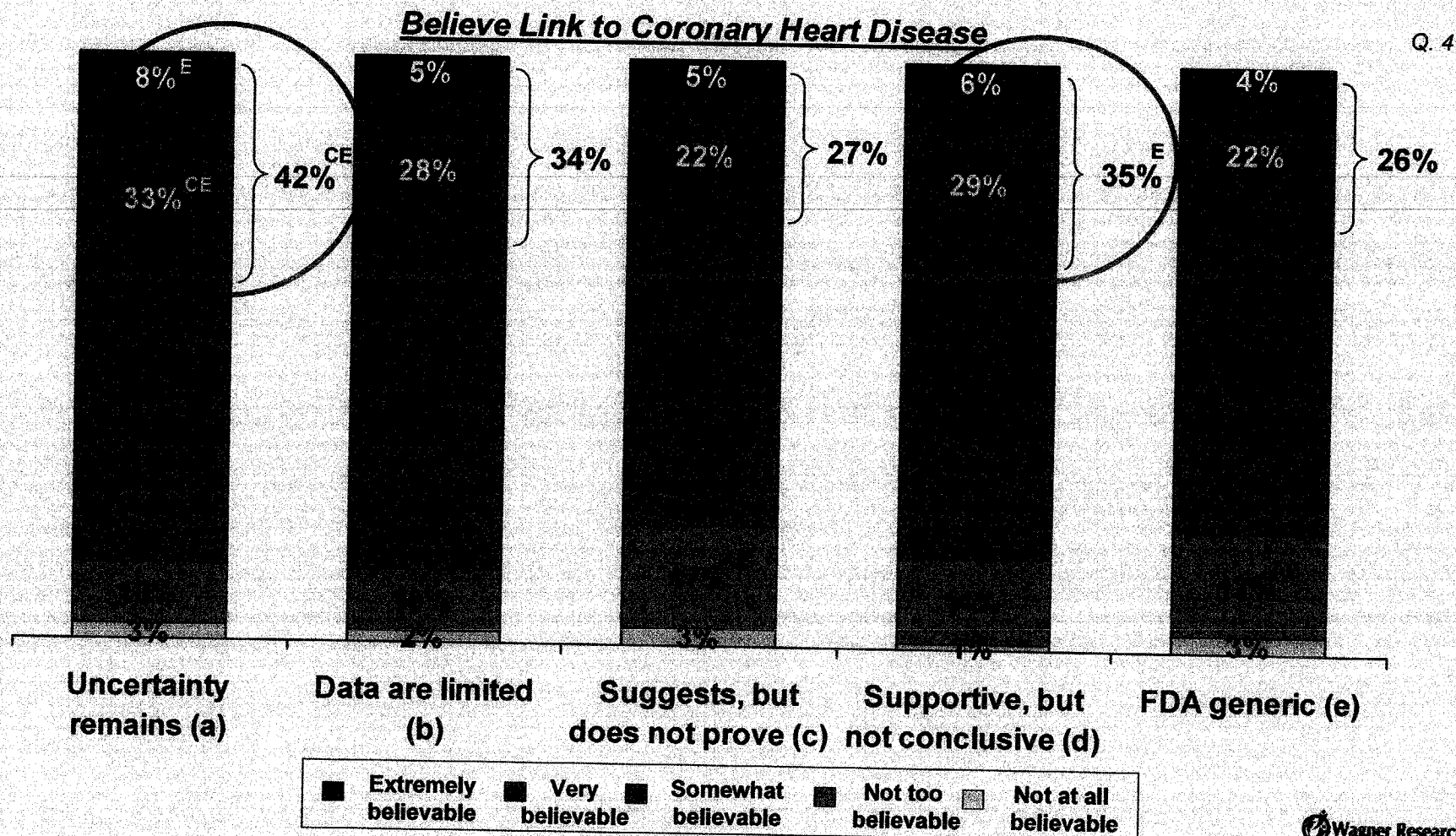


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Believability of Link to Coronary Heart Disease – Monadic Scores

- Uncertainty Remains and Supportive, But Not Conclusive generate a higher level of assurance about the link to coronary heart disease than does the FDA Generic.



Base: Total Rated Claim (Monadic) – approximately 200 per claim

Uppercase letters indicate a significant difference at the 95% confidence level (a/b/c/d/e)

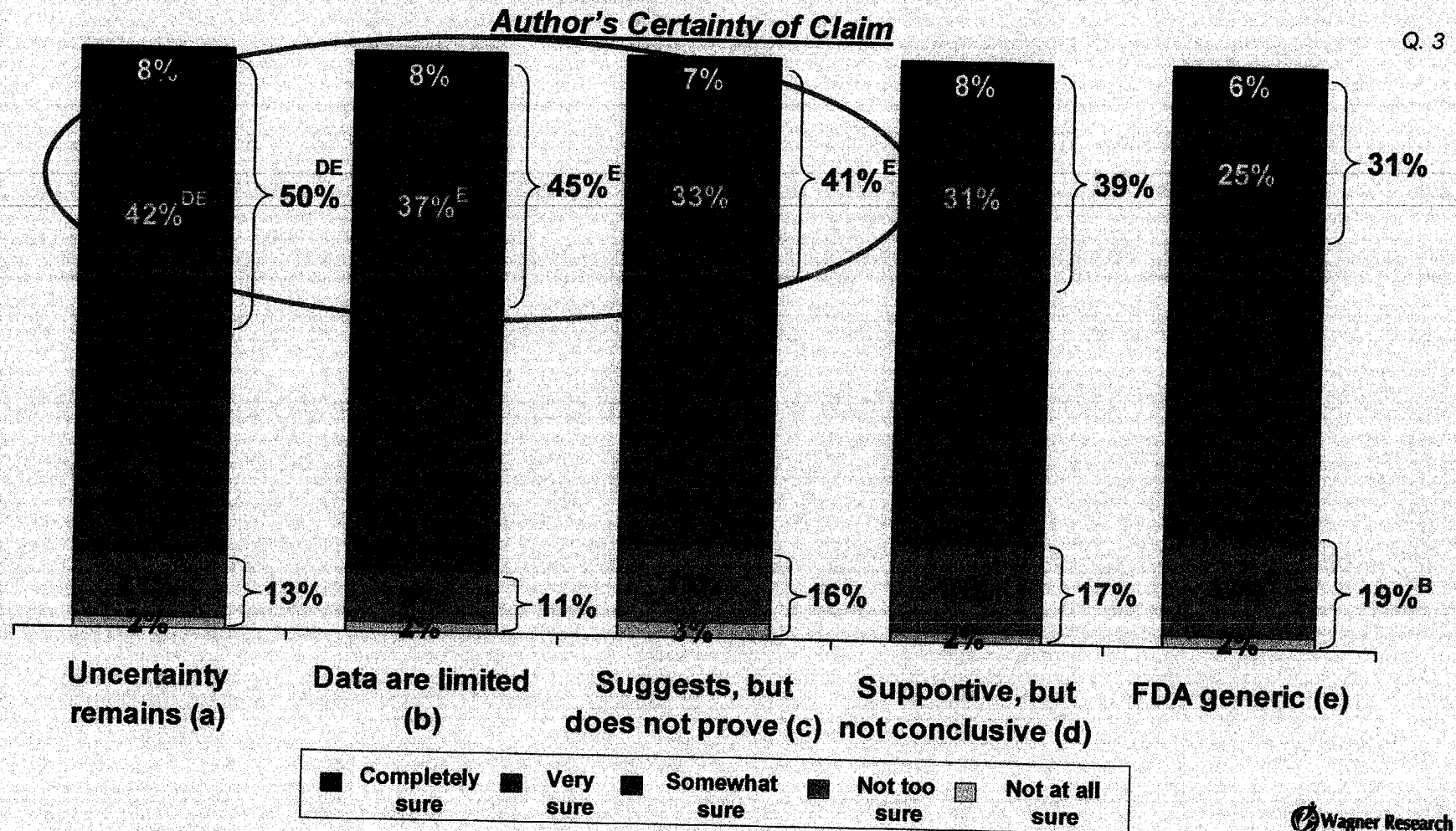


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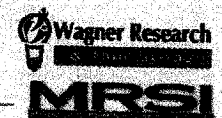
Author's Certainty that Canola Oil helps reduce the risk of heart disease –*Monadic Scores*

- On a monadic basis with no point of comparison, *Supportive, but Not Conclusive* is the only alternative statement that conveys the same level of certainty regarding the reduced risk of heart disease as does the *FDA Generic*.



Base: Total Rated Claim (Monadic) – approximately 200 per claim

Uppercase letters indicate a significant difference at the 95% confidence level (a/b/c/d/e)



"Health Claims" Study (# 05_080)

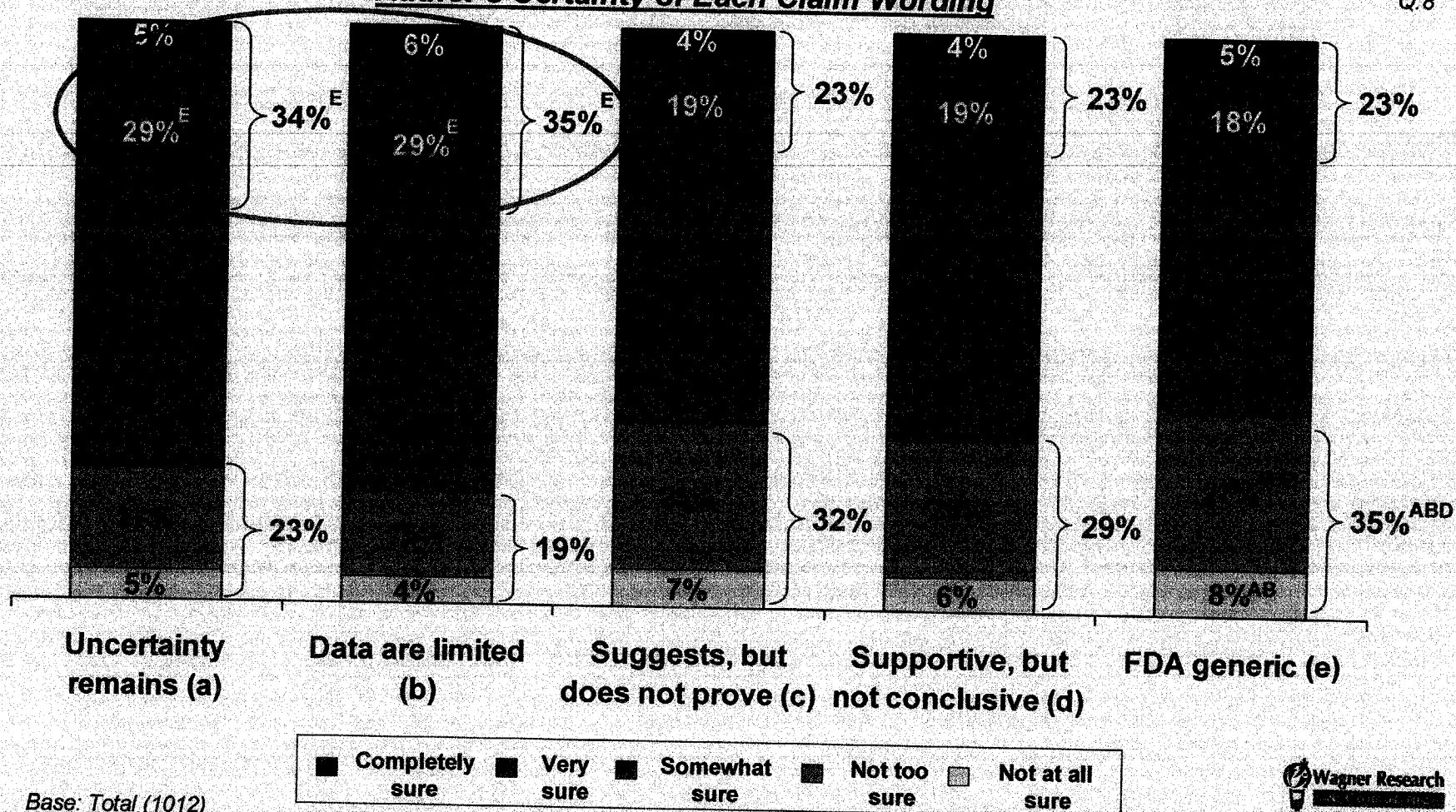


Author's Certainty that Canola Oil helps reduce the risk of heart disease – *Comparative Monadic Scores*

- However, on a comparative monadic basis in which all 1000+ respondents rated each of the five statements on the level of certainty conveyed, *Suggests but Does Not Prove* and *Supportive but Not Conclusive* were both at parity to the *FDA Generic* statement.

Author's Certainty of Each Claim Wording

Q.8



Base: Total (1012)

Uppercase letters indicate a significant difference at the 95% confidence level (a/e, b/e, c/e, d/e)



"Health Claims" Study (# 05_080)

Demographics



Demographics

	Total	Statement Seen				
		Uncert. Remains	Data are Limited	Sugg., but does not prove	Supp., but not conclusive	FDA Generic
Base: Total	(1012)	(202)	(205)	(202)	(201)	(202)
	%	%	%	%	%	%
		(a)	(b)	(c)	(d)	(e)
Age						
21-34	33	33	33	32	32	33
35-54	51	50	50	51	50	51
55-64	17	16	17	17	17	17
Region						
Northeast	19	19	18	20	19	19
Midwest	23	23	24	23	23	23
South	36	36	35	37	36	36
West	22	22	22	21	21	21
Ethnicity						
White/Caucasian	81	81	79	80	82	83
Black/African American	11	10	11	10	10	13
Asian Or Pacific Islander	3	3	3	3	2	2
Mixed Racial Backgorund	3	3	2	3	5 ^E	1
Some Other Race	3	4	4	5 ^E	2	1
Hispanic	9	10	9	9	10	6

Wagner Research

MRSI

Uppercase letters indicate a significant difference at the 95% confidence level (a/b/c/d/e)